



# Interim Guidance for the use of Monoclonal Antibodies for Treatment of COVID-19 (January 15, 2021)

Monoclonal antibodies are proteins made by immune cells in response to pathogens. They work by binding to viral targets that are used to enter cells and inhibit infection. Patients who are hospitalized with COVID-19 have been found to have high viral loads and thus, monoclonal antibodies were developed to reduce viral burden based on the hypothesis that reducing the amount of virus would lead to clinical improvement.

## Key Facts

- There are two products that have currently received emergency use authorization (EUA) from the FDA for the treatment of mild to moderate COVID-19
  - Eli Lilly's Bamlanivimab is a single antibody therapy
  - Regeneron's Casirivimab/Imdevimab is a mixture of two antibody therapies
- Both products require intravenous infusion over 60 mins and continued observation for one hour afterwards with an estimated real-world treatment time of three hours
- Both products are authorized for the treatment of mild to moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive test results of direct SARS-CoV-2 viral testing and who are at high risk for progressing to severe COVID-19 and/or hospitalization.
- Anyone 65 years or older with mild to moderate COVID-19 (i.e. not hospitalized and not requiring oxygen due to COVID-19) is considered high risk for progression to severe COVID-19 per the EUA. Thus, monoclonal antibody therapies may be especially useful for skilled nursing and assisted living facilities.
- Both should be given to eligible patients within 10 days of symptom onset
- Both have a rare risk of serious hypersensitivity reaction, including anaphylaxis
- Both treatments are available to facilities in NC through NC DHHS at no cost
- Providers can bill Medicare for the administration fee for either infusion

## FDA Emergency Use Authorization (EUA)

The FDA has issued EUA for monoclonal antibody therapies for use in high-risk outpatients with COVID-19. Bamlanivimab and casirivimab/imdevimab are monoclonal antibody therapies that work directly to neutralize the SARS-CoV-2 virus in the body and may decrease the incidence of ED visits and hospitalizations in patients at greatest risk for progression to severe disease. Under the EUA, **eligible patients are outpatients with mild and moderate COVID-19 with no more than 10 days of symptoms, and the therapies should be administered as soon as possible after positive viral test for COVID-19.**

These patients must be at high-risk for progressing to severe COVID-19 and/or hospitalization due to age, elevated BMI, or specified chronic conditions (definitions [here](#) and [here](#), respectively). Notably, the EUA is not an approval but a determination that potential benefits outweigh potential risks. Also, given low numbers of clinical events in Phase 2 trials done thus far, both the degree of benefit and who would benefit the most is not certain.

## The Therapies

### 1. Bamlanivimab

The FDA first [issued an EUA](#) for bamlanivimab, which is manufactured by Lilly. Bamlanivimab is a neutralizing monoclonal antibody that binds to the receptor binding domain of the spike protein of SARS-CoV-2. The EUA was based on an interim analysis from the BLAZE-1 phase 2 randomized, double-blind, placebo-controlled clinical trial in 465 non-hospitalized adults with mild to moderate COVID-19 symptoms. For patients at high risk for disease progression, hospitalizations and emergency room visits occurred in 3% of bamlanivimab-treated patients on average compared to 10% in placebo-treated patients.” The safety in the antibody group was similar to the placebo group. The published NEJM research paper is found [here](#).

### 2. Casirivimab and Imdevimab

The FDA later [issued an EUA](#) for casirivimab and imdevimab, which is manufactured by Regeneron and is given as a single infusion. Casirivimab and imdevimab are two recombinant human monoclonal antibodies that bind to non-overlapping epitopes of the spike protein receptor binding domain of SARS-CoV-2. The EUA was based on an interim analysis of Phase 1/2 randomized, double-blinded, placebo-controlled trial in 799 non-hospitalized adults with mild to moderate COVID-19 symptoms. Per the EUA: “For patients at high risk for disease progression, hospitalizations and emergency room visits occurred in 3% of casirivimab and imdevimab-treated patients on average compared to 9% in placebo-treated patients.” The safety in the antibody group was similar to the placebo group. The published NEJM research paper is found [here](#).

## Obtaining Monoclonal Antibody Products in North Carolina

Allocation and distribution of bamlanivimab and casirivimab/imdevimab are controlled by the United States Department of Health and Human Services (US HHS). Every two weeks US HHS virtually allocates a quantity of both monoclonal antibody products to NC DHHS. NC DHHS then works to allocate these monoclonal antibody products to interested providers across the state. Confirmed orders are communicated by NC DHHS to AmerisourceBergen who serves as the sole contracted distributor for this initiative. Product is then delivered directly to the provider within about 1 week.

**Providers interested in obtaining monoclonal antibodies can complete this short account setup survey:** <https://nc.readyop.com/fs/4d5E/f8fc>. This information will be used to initiate account creation/setup with AmerisourceBergen. Once your information is received someone from NC DHHS will contact you to provide further instruction.

## NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

Providers receiving and administering COVID-19 monoclonal antibody therapeutics are required to report inventory and administration data to NC DHHS on a weekly basis. This inventory reporting is done via electronic survey emailed to location points of contact every Tuesday. This information is necessary to track inventory and usage for the purpose of informing future allocations.

By completing the account setup survey and accepting an allocation from NC DHHS you are indicating that you have read and understand the EUA documents in full, that your facility is capable and handling/administering these monoclonal antibody therapies in accordance with the EUA requirements and you agree to report your inventory/use data to NC DHHS on a weekly basis.

### Federal Monoclonal Antibody Initiative:

HHS/ASPR has also implemented a program at the federal level called Special Projects for Equitable and Efficient Distribution (SPEED). The goal of the SPEED initiative is to assist states in identifying non-hospital facilities that serve priority populations such as nursing homes, dialysis centers and Federally qualified health centers (FQHCs). Through SPEED, providers who serve these priority populations may be eligible for their own direct allocation of monoclonal antibodies from the federal government.

Providers seeking more information about the SPEED program should visit:

<https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Pages/SPEED.aspx>.

### Additional Resources:

[Bamlanivimab EUA Fact Sheet for Health Care Providers](#)

[Bamlanivimab EUA Fact Sheet for Patients, Parents and Caregivers](#)

[Frequently Asked Questions on the Emergency Use Authorization for Bamlanivimab](#)

[HHS ASPR's Bamlanivimab website](#)

[Casirivimab/Imdevimab EUA Fact Sheet for Health Care Providers](#)

[Casirivimab/Imdevimab EUA Fact Sheet for Patients, Parents and Caregivers](#)

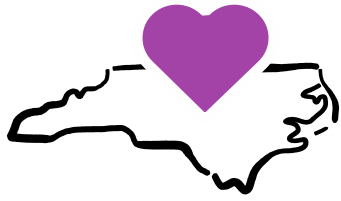
[Frequently Asked Questions on the Emergency Use Authorization for Casirivimab and Imdevimab](#)

[HHS ASPR's Casirivimab/Imdevimab website](#)

[Centers for Medicare & Medicaid Services \(CMS\) Monoclonal Antibody COVID-19 Infusion Guidance](#)

[National Infusion Center Association COVID-19 Antibody Therapies Resource Center](#)

**For more information, please contact Tim Davis ([tim.davis@dhhs.nc.gov](mailto:tim.davis@dhhs.nc.gov)).**



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